REMARKS

This Amendment is submitted in response to the Non-Final Office Action mailed on October 19, 2004. Claims 18, 20-22 and 24 are pending in this application. Claims 1-17 have been withdrawn previously. Claims 19 and 23 have been canceled previously.

Claims 18, 20-22 and 24 are rejected under 35 U.S.C. §112, first and second paragraphs. In response, Applicants have amended Claim 18 to provide a method of treatment or prevention of a disorder of the gastrointestinal tract of a mammal by mediation of lipopolysaccharide interaction with the gastrointestinal tract in a mammal in need thereof which comprises the step of orally administering to the mammal an effective amount of a CD14 variant or fragment thereof having no O-glycosylation.

As acknowledged by the Patent Office, the Specification is enabling for a method of treating against intestinal bacterial infection. Similar to intestinal bacterial infection, the examples of GI tract disorders set forth in the Specification at, for example, page 9, lines 14-22, are GI tract disorders that can be treated or prevented by effective mediation of lipopolysaccharide interaction with the gastrointestinal tract. See also Specification, page 2, lines 25-28. These examples of GI tract disorders include inflammatory bowel disease, Chrone's disease, ulcerative cholitis, coeliac disease, intestinal bacterial overgrowth, chronic hepatitis, necrotising enterocolitis, neonatal sepsis, infectious diarrhoea, disbalance of the intestinal microflora, allergic reactions to food and bacterial translocation from the gut to other compartments of the body. As provided in the statement and accompanying publication of the inventors attached as Exhibits A and B to the previously filed Amendment dated December 1, 2003, any factor capable of modulating responses to bacteria or their components, such as lipopolysaccharide, may be used in the prevention and/or treatment of these disorders. See also, Specification at, for example, page 8, lines 6-28. Accordingly, Claim 18 is now directed to a method of treating or preventing GI tract disorders that can be treated or prevented by effective mediation of lipopolysaccharide interaction with the gastrointestinal tract.

Claim 18 now includes the step of administering to a mammal an effective amount of a CD14 variant or fragment thereof having no O-glycosylation. The Specification discloses the method of the claimed invention in reference to at least "mammals" at, for example, p. 9, lines

14-17. Accordingly, Applicants have amended Claim 18 to refer to a "mammal" to which the method of Claim 18 is directed.

Claim 21 has been amended to clarify that the CD14 variant or fragment thereof is at least 70% homologous with the amino acid sequence of human serum CD14. Claim 21 has been further amended to clarify that the amino acid sequence of human serum CD14 includes SEQ ID NO:1. Support for these amendments can be found in the Specification at, for example, page 4, lines 5-7 and lines 25-29.

Claim 22 has been amended to clarify that the method of Claim 18, can include the step of administering a composition comprising a protein that does not include O-glycosylation and has an amino acid sequence that is at least 70% homologous with human serum CD14. Additionally, Claim 22 has been further amended to clarify that the amino acid sequence of human serum CD14 includes SEQ ID NO:1.

Based on at least these reasons, Applicants believe that the written description and enablement requirements under 35 USC §112 have been satisfied and that the rejections under 35 USC §112, first and second paragraphs should be withdrawn.

The Patent Office has maintained its rejection of Claim 18 under 35 USC §102 as allegedly anticipated by the publication to Haziot et al. ("*Haziot*"). In light of the instant amendment, Applicants believe that this rejection is improper.

As stated in the previous Amendment dated December 1, 2003, Applicants believe the cited art is distinguishable from the claimed invention for a number of reasons. For example, the primary focus of the cited art relates to a recombinant soluble CD14 that, if injected into mice, can purportedly reduce mortality due to lipopolysaccharide injection. *Haziot* does not teach that CD14 can be utilized to effectively prevent or treat GI tract disorders by modulating responses to lipopolysaccharide in the gastrointestinal tract as in the claimed invention. Furthermore, *Haziot* does not teach oral administration of CD14 as in the claimed invention. Therefore, *Haziot* does not anticipate the claimed invention.

Claims 18, 20-22 and 24 are rejected under 35 USC §102 as allegedly anticipated by PCT application No. WO 98/22580 to Julius et al. ("*Julius*"). Applicants submit that the rejection is no longer proper in view of the amended Claim 18, and such rejection should be withdrawn.

As stated in Applicants' Specification at page 3, line 30 through page 4, line 4, *Julius* does not describe a CD14 variant having no O-glycosylation as in the claimed invention. In addition, *Julius* does not teach that CD14 can be utilized to effectively prevent or treat GI tract disorders by modulating responses to lipopolysaccharide in the gastrointestinal tract as in the claimed invention. Instead, *Julius* discloses the presence of a protein in bovine colostral whey which can be used to activate B-cells in a patient having T-cell immune deficiency. Therefore, for at least these reasons, *Julius* fails to anticipate the claimed invention.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Accordingly, Applicants respectfully request that the anticipation rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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